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CONFIDENTIALITY CONCERNS RAISED BY DNA-BASED TESTS IN THE MARKET-DRIVEN MANAGED CARE SETTING

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ABSTRACT

In a policy climate where incentives to cherry pick are minimized, Managed Care Organizations can implement practices that safeguard medical privacy to the extent that data is protected from falling into the hands of third parties who could misuse it to discriminate. To the extent that these practices have been codified into the regulatory framework of the Health Insurance Portability and Accountability Act (HIPAA) consumers may be able to rest easy about their genetic data being revealed to third parties who may discriminate. However, there are limitations to the use of policy instruments to prevent the discrimination of an entire genre of clients by market driven managed care organizations. Policy measures, to assure that knowledge of genetic conditions and their future costs would not be used by market driven managed care organizations to implement institutional policies and products that would implicitly discriminate against a genre of clients with genetic conditions, present difficulties.

A. The function of confidentiality in health care:

Medical confidentiality practices have traditionally served to protect several values in health care. These include: trust in the doctor patient relationship based in the faith that sensitive personal information revealed to the doctor in the course of seeking health care will not be revealed further where it could be used to stigmatize the patient and discriminate against this person. In addition, confidentiality practices have served to protect patient autonomy and dignity by allowing the patient the privacy to conduct his or her life without pressure from others. With the rise of the practice of informed consent

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has increasingly been sought prior to release of confidential information. Confidentiality practices in health care, therefore, serve the values of trust, autonomy, patient dignity, and protection from discrimination and stigmatization. (Kotval, Jeroo. 2005. Genetic privacy in the health care system. In, Sheldon Krimsky and Peter Shorett, eds., Rights and Liberties in the Biotech Age: why we need a genetic bill of rights. Lanham, MD: Rowman & Littlefield Publishers, c 2005).

The rise of market-driven managed care as a major institution for delivering health care in the late twentieth and early twenty-first century raises several concerns related to medical confidentiality. This institution is the descendent of commercial insurers who have a history of cherry picking health clients through a variety of means such as risk rating and selective marketing. To this, managed care has added a host of strategies to shift costs to patients and shifting risks to providers by implementing co-payments and deductibles for clients and capitated payments for physicians.

The advent of pre-symptomatic and predispositional genetic testing, with its capacity for providing information about the future health status of individuals, would be of interest to such an institution since these tests can identify future patient costs. Hence, Kotval has referred to market-driven managed care organization as "double agents" since they at the same time claim to provide quality care and save costs. (See Kotval, J.S. "Market-driven managed care and confidentiality of genetic tests: the institution as double agent," Albany Law Journal of Science and Technology, 1998, Volume 9, No1, pages 1-25). The availability of this information electronically only increases the ease with which it can be transmitted and manipulated and hence increases the risk for harm to individuals because of a knowledge of their genetic make-up.

B. Study of managed care organizations in New York State:

We have completed a study of managed care organizations in New York State to examine the confidentiality practices of these institutions operating in a mature and uniform policy environment. Policies that reliably protect medical confidentiality must not only address the security of the health data, including unauthorized disclosures, they need to address the illegitimate internal use of such data for non-medical purposes and the institutional incentives to abuse confidentiality. Only then can we be assured that the umbrella of values upheld through traditional confidentiality practices are safeguarded.

Major elements of the New York State policy framework governing this include:

- Prohibit use of health status information in determining eligibility for health insurance,
- Prohibit use of genetic test information in asymptomatic individuals to determine access to health insurance; i.e., a positive genetic test in an asymptomatic individual cannot be deemed a preexisting condition,

- Guarantee renewal of individual insurance regardless of health status or claims experience,

- Require all HMOs to offer a standard set of benefits for individual insurance products,

- Require individual insurance plans to be community rated.

Further, informed consent laws provide protections to persons from use of genetic information without their consent. Insurance laws also restrict who can request genetic testing and who may use test results and for what purpose. New York State Civil Rights law further offers protections on the performance of genetic tests including specifying what constitutes informed consent. Re-disclosure of test results to other parties without individual consent is prohibited.

As a result of this policy framework incentives to use member medical information for other than health purposes, such as structuring benefit packages, may be eliminated in New York State. How does this translate into privacy practices within the institutions?

We initially contacted 20 health plans and completed an in-depth study of seven. The study design included obtaining information from health plans using structured interview question based on health privacy recommendations from national organizations. Interview questions sought answers to questions related to the management, security, and utilization of medical information. In addition we reviewed a variety of materials from twenty-three plans to analyze their practices related to medical confidentiality. These documents, such as subscriber contracts and member handbooks, were reviewed for content related to medical records use and procedures and notice given to members on protecting confidentiality.

We especially sought to (1) discover potential gaps in protecting genetic information, (2) identify the limits of any regulatory policy to protect confidential genetic test information, and (3) identify best practices targeted to achieving both an actual and cultural shift in organizational practice.

[HIGHLIGHTS OF FINDINGS REGARDING CONFIDENTIALITY PRACTICES OF NEW YORK STATE MCOs:

Who has access, how much, and how is this access to information obtained?

- All enrollment contracts have provisions for health plan subscribers to authorize release of medical information to health plan at time of enrollment.

- Staff within the Managed Care Organization have access to

personal health information including encounter data though the level of access to detailed personal health information is restricted to personnel in a managed organization by job function. In an electronic system, this is done by password protections and limits on data fields they can access. For example, utilization review and disease management staffs appear to have the most access to individual clinical information. Most health plans have specific policies and procedures for internal disclosure of individually identifiable medical information.

- Health plan requests for patient medical information from providers are limited to minimum amount needed to make decisions and administer benefit contract. This is subject to the needs of the plan if the benefit determination is contested. Patient medical information is therefore exposed to the health plan during the appeals process subject to "informed consent" by the patient.

- Health plans do not routinely receive or ask for results of diagnostic tests, including genetic tests and access to the full medical record from physician office is sought only in a very limited number of cases and is subject to the providers discretion. Situations where such access is sought would include suspicions of fraud, or where extensive disease management is necessary. Patient consent in such cases is not required.

- Release of genetic test results by testing provider is controlled by legally mandated informed consent procedures where the patient is required to provide written informed consent for each disclosure of genetic information. Health plans do not have access to this information without specific member consent according to New York State law.

Do managed care organizations have a culture of care for medical privacy?

- Member materials on use and disclosure of personal information by the health plan do not address the concerns that the public seems to have about confidentiality of personal information.

- An organizational culture which values confidentiality as important to a relationship with members is not easily apparent in individual managed care organizations.

- Nevertheless, consumer concerns over inappropriate use of genetic information by managed care organizations in New York State may be unfounded at this time because of the current regulatory environment and limited use of genetic information by most providers and health plans.

- Health plan personnel receive training regarding confidentiality practices and procedures. However, concerns about obtaining and disclosing genetic information specifically is generally lacking.

- Some health plan policies and procedures do not explicitly address internal disclosure of any individually identifiable medical information to health plan staff for non-health purposes. Similarly, some health plans do not have adequate formal policies and procedures for release of individually identifiable information to employers (including self-funded plans). These policies are covered under the plan's general procedures for release to third parties.

Conclusions:

Our findings indicate that in a policy climate where incentives to cherry pick are minimized institutions can implement practices that safeguard medical privacy to the extent that data is protected from falling into the hands of third parties who could mis-use it to discriminate. To the extent that these practices can be codified into a legislative or regulatory policy framework consumers may be able to rest easy about their genetic data being revealed to third parties who may discriminate. However, this knowledge is accessible to MCOs themselves and could be used to re-structure benefit packages, increase overall costs or dramatically change the way in which employers cover health insurance. These possibilities justify consumer concerns about use of genetic information to disenfranchise them from the health care system. Only guaranteed universal health care can assuage these concerns in the long run.

Publications:

Kotval, Jeroo, 2005. Genetic privacy in the health care system. In, Sheldon Krimsky and Peter Shorett, eds., *Rights and Liberties in the Biotech Age: why we need a genetic bill of rights.* (Rowman & Littlefield Publishers, c 2005).

DeLaMarter, C.M. and J.S. Kotval, 2001. Management and use of confidential medical information in New York State managed care organizations: can we rest easy in the genetic age? Under revision .

McNutt, L.A., Carlson, B.E., and Kotval, J.S., 2001. Written informed consent forms for survey research: information or information overload? Under revision.

Kotval, J.S. Genes for Sale? Ethics, society and genetic technology. Albany Magazine, Fall 2000.

Kotval, J. S. 1998. Market-driven managed care and the confidentiality of genetic tests: the institution as double agent. Alb. L.J. Sci. and Tech. 9(1): 1 - 25.

Kotval, J.S. 1998. The human genome project and genetic tests: no easy choices.• Feature Article. Society for Industrial Microbiology News, 48(4), July/August, 1998.

Invited Talks based on the grant award:

" Recruitment and Retention of Minority Graduate Students in the Sciences," Workshop Presented at The Human Genome Project Conference sponsored by the National Education Foundation of Zeta phi Beta Sorority, Washington, D.C. November 10, 2001.

"Genomics and Market Institutions: some sobering implications,"presented at Pennsylvania Black Caucus – summit 2001: An Information Conference on the Human Genome Project, October 6, 2001.

" The implications of public health genetics for minority communities," Presented at Pennsylvania Black Caucus – summit 2001: An Information Conference on the Human Genome Project, October 5, 2001.

"Can Market-driven institutions deliver just health care in the genomics age?" Presented at the Human Genome Project Conference, sponsored by the Zeta Phi Beta Sorority, Atlanta, Ga. July 21, 2001.

"Experiences educating minority graduate students in the sciences," Workshop Presented at the Human Genome Project Conference, sponsored by the Zeta Phi Beta Sorority, Atlanta, Ga. July 20, 2001.

"Social justice concerns in the genomics age," Presented at 'The Human Genome Project: an information conference' sponsored by Zeta Phi Beta Sorority National Education Foundation, Center for Minority Health Research Education and Training, SUNY-Albany, and Health Policy consortium of the Capital Area. May 18, 2001.

"Ethical issues raised by public health genetics," Presented at Sarah Lawrence College, Mini course on the Human Genome Project. April 9, 2001.

"Genomics and market-driven health care: ethical concerns," Presented at "The human genome project an information conference: The challenges and impact of human genome

research for the minority communities," Philadelphia, Pa. July 7 - 8, 2000.

"Privacy and confidentiality in the informatics age," Presented at the 2000 GENES conference on 'Genomics and Informatics,' New York, NY. June 16, 2000.

"Ethical issues raised by DNA-based tests," Presented at the Medical Ethics Grand Rounds, Albany Medical Center, Albany, NY. May 18, 2000.

"Ethical issues raised by the human genome project," Presented at the Delmar Institute for Life Long Learning, November 17, 1999. (At the invitation of Professor Bonnie Steinbock, Chair, Philosophy Department, University at Albany).

"The ethical implications of institutionalizing market-driven managed care in the age of genetic testing," Presented at the Annual Colloquium, International Association for Research in Economic Psychology, Belgirate, Italy. June 30, 1999 - July 3, 1999.

"The human genome project and genetic tests: no easy choices," Society for Industrial Microbiology News, 48(4), July/August, 1998.

"Medical Records Practice in Managed Care Settings," Presented at the Einstein Institute for Science, Health and the Courts: the genetics adjudication project, Cape cod, Ma. August 7 - August 12, 1998.

"Confidentiality concerns raised by DNA-based testing in the market-driven managed care setting." Presented at the DOE Human Genome Project Grantees Conference, Santa Fe, New Mexico, Nov. 1997.